Substitute for form 1449/PTO & 1449B/PTO

FIRST INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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6,407,079

4.870.060

4.727.064

4,596,795

4.764.604

4.226.848

4.250.163

4,535,152

5,401,724

Signature

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plication Number	10/551,094		
ng Date			
st Named Inventor	Nicholas S. Bodor		
aminer Name			
orney Docket No.	1033935-000020		

06-18-2002

09-26-1989

02-23-1988

06-24-1986

08-16-1988

10-07-1980

02-10-1981

08-13-1985

03-28-1995

Sheet U.S. PATENT DOCUMENTS Kind Code Evaminer Document Name of Patentee or Applicant Issue/Publication Date Initials Number (if known) (MM-DD-YYYY) of Cited Document 4.383.992 Lipari 05-17-1983 6,239,118 **B1** Schatz et al. 05-29-2001 5,424,296 Saven et al. 06-13-1995 5.510.336 Saven et al. 04-23-1996 5,506,214 Beutler 04-09-1996 4,659,696 Hirai et al 04-21-1987 3,459,731 Gramera et al. 08-05-1969 4.478.995 Shinoda et al. 10-23-1984 5,310,732 Carson et al. 05-10-1994 5.401.724 Beutler 03-28-1995 5.106.837 Carson et al. 04-21-1992 4.497,803 Harada et al 02-05-1985 6.194.395 **B1** Schultz et al. 02-27-2001

Müller et al.

Müller

Pitha

Pitha

Müller

Nagai et al.

Nagai et al.

Szejtli et al.

Beutler

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FOREIGN PATENT DOCUMENTS											
				STATUS							
Examiner Initials	Document Number	Kind Code (if known)	Country	Date of Publication (MM-DD-YYYY)	Translation	Partial Translation	Eng. Lang. Summary	Search Report	IPER	Abstract	Cited in Spec
	0 197 571	A2	EP	10-15-1986						_	X
	90/12035	A1	WO	10-18-1990							×
	31 18 218	A1	DE	04-22-1982						Х	Х
	33 17 064	A1	DE	11-15-1984	_					Х	Х
	2 189 245	Α	UK	10-21-1987							X
	0 149 197	B1	EP	07-24-1985	Х						X
	0 094 157	A1	EP	11-16-1983					-		X

NON-PATENT LITERATURE DOCUMENTS					
Examiner Initials	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.				
	Tarasiuk et al., "Stability of 2-Chloro-2'-Deoxyadenosine at Various pH and Temperature", Archivun				
	Immunologiae et Therapiae Experimentalis, Vol. 42, pp. 13-15, 1994, published by Birkhauser				
	Publishers Ltd., Basel, Switzerland				

Considered

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with M.P.E.P. § 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

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FIRST INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 2 of 2

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Application Number	10/551,094	-	
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irst Named Inventor	Nicholas S. Bodor		
xaminer Name			
Attorney Docket No.	1033935-000020		

	NON-PATENT LITERATURE DOCUMENTS				
Examiner Initials	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.				
	Romine et al., "A Double-Blind, Placebo-Controlled, Randomized Triel of Cladribine in Relapsing- Remitting Multiple Sclerosis", Proceedings of the Association of American Physicians, Vol. 111, No. 1, pp. 35-44, 1999, published by Blackwell Publishing, Malden, MA				
	Tortorella et al., Current Opinion on Investigational Drugs, 2(12), pp. 1751-1756, 2001, published by PharmaPress Ltd., London, GB				
	Selby et al., "Safety and Tolerability of Subcutaneous Cladribine Therapy in Progressive Multiple Sclerosis", Can. J. Neurol Sci., Vol. 25, pp. 295-299, 1998, published by Canadian Journal of Neurological Science, Calgary, Canada				
	Rice et al., "Cladribine and progressive MS Clinical and MRI outcomes of a multicenter controlled trial", Neurology, Vol. 54, pp. 1145-1155, 2000, published by Lippincott Williams and Wilkins, Hagerstown, MD				
	Liliemark et al., "On the Bioavailability of Oral and Suboutaneous 2-Chloro-2'-Deoxyadenosine in Humans: Alternative Routes of Administration", Journal of Clinical Oncology, Vol. 10, No. 10, pp. 1514-1518, 1992, published by American Society of Clinicial Oncology, Alexandria, Vol. 10, No. 10, pp. 1514-1518, 1992, published by American Society of Clinicial Oncology, Alexandria, Vol. 10, No. 10, pp. 1514-1518, 1992, published by American Society of Clinicial Oncology, Alexandria, Vol. 10, No. 10, pp. 1514-1518, 1992, published by American Society of Clinicial Oncology, Alexandria, Vol. 10, No. 10, pp. 1514-1518, 1992, published by American Society of Clinicial Oncology, Alexandria, Vol. 10, No. 10, pp. 1514-1518, 1992, published by American Society of Clinicial Oncology, Alexandria, Vol. 10, No. 10, pp. 1514-1518, 1992, published by American Society of Clinicial Oncology, Alexandria, Vol. 10, No. 10, pp. 1514-1518, 1992, published by American Society of Clinicial Oncology, Alexandria, Vol. 10, No. 10, pp. 1514-1518, 1992, published by American Society of Clinicial Oncology, Alexandria, Vol. 10, No. 10, pp. 1514-1518, 1992, published by American Society of Clinicial Oncology, Alexandria, Vol. 10, No. 10, pp. 1514-1518, 1992, pp. 1514-1518, pp. 1514-1518, pp. 1514-15				
	Karlsson et al., "Oral cladribine for B-cell chronic lymphocytic leukaemia: report of a phase II trial with a 3-d, 3-weekly schedule in untreated and pretreated patients, and a long-term follow-up of 126 previously untreated patients", British Journal of Haematology, Vol. 116, pp. 538-548, 2002, published by Blackwell Science Ltd., Oxford, UK				
	Lillemark, "The Clinical Pharmacokinetics of Cladribine" Clin. Pharmacokinet, Vol. 32 (2), pp. 120-131, 1997, published by Adis International Limited, Wolters Kluwer Health, Yardley, PA				
	Nogradi, "Dimethyl-β-Cyclodextrin", Drugs of the Future, Vol. 9, No. 8, pp. 577-578, 1984, published by JR Prous SA Publishers, Barcelona, Spain				
	Nakai et al., "Effects of Grinding on the Physical and Chemical Properties of Crystalline Medicinals with Microcrystalline Cellulose V: Comparison with Tri-O-methyl-B-cyclodextrin Ground Mixtures". Chem. Pharm. Bulletin, Vol. 28(5), pp. 1552-1558, 1980, published by Pharmaceutical Society of Japan, Tokyo, Japan				
	Saenger, "Clyclodextrin Inclusion Compounds in Research and Industry", Angew. Chem. Int. Ed. Engl., Vol. 19, pp. 344-362, 1980, published by Verlag Chemie, GmbH, Weinheim, Germany				

Examiner Signature	/Nathan Schlientz/	Date Considered	03/16/2010	